JAN 1 2 2004

DUPLICATE

BioCentrex

6100 BRISTOL PARKWAY, CULVER CITY, CA 90230 TEL 310.258.9707 FAX 310.258.9707

Cardiac Panel System 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K033155

Submitters Name and Address

BioCentrex LLC
6100 Bristol Parkway
Culver City, CA 90230
Telephone: 310-258-9702
Fax: 310-258-9707
Contact: Thomas Grove Ph.D.

Date Prepared: September 29, 2003

Device Names

Proprietary Name: *BioCentrex* Cardiac Panel System

Common Name:Cardiac Troponin I, CK-MB, and Myoglobin Immunoassays

Classification Name: Fluorometric method; cardiac troponin I, CK-MB, and myoglobin; Cardiac panel performed on the *BioCentrex* Analyzer

Predicate Device:

Access® AccuTnI™ for Use on the Access® Immunoassay Analyzer
510(k) Number: K021814

Access® CK-MB for Use on the Access® Immunoassay Analyzer
510(k) Number: K000716

Access® Myoglobin for Use on the Access® Immunoassay Analyzer
510(k) Number: K951634

Device Description:

BioCentrex Cardiac Panel cartridges are used with the *BioCentrex* Analyzer to measure cardiac troponin I (cTnI), creatine kinase-MB, and myoglobin concentrations in whole blood, serum or plasma specimens.

Intended Use:

The *BioCentrex* Cardiac Panel cartridge is intended for *in vitro* diagnostic use with the BioCentrex Analyzer to quantitatively measure cardiac troponin-I, creatine kinase MB and myoglobin concentrations in anti-coagulated whole blood, serum or plasma.

Comparison of Technological

	BioCentrex cTnI	Access® AccuTnI
Intended Use	For *in vitro* diagnostic use. To measure cardiac troponin I in whole blood, plasma or serum	Same
Indications	Diagnosis of AMI.	Same
Measurement	Quantitative	Same
Method Principle	2-Site sandwich immunoassay	Same
Method Detection	Fluorescence detection on a planar waveguide.	Chemiluminescent enzyme immunoassay
Detector	CCD camera	Luminometer
Specimen dilution	Not required	Same
Key Materials	Mouse monoclonal anti-human cTnI antibodies	Same
Test time	12 minutes	15 minutes
Sample Type	Anti-coagulated whole blood, serum, or plasma	Serum and Plasma
Specimen volume	200 µL	160 µL
Calibration	Calibration information bar-coded. New calibration for each lot.	6-level liquid calibration every 28 days
Quality Control	None	One level
Reporting Units	ng/mL	Same
Reaction Temp.	30 °C	37°C

Summary of Analytical Studies:

Precision:

Cardiac Troponin I – Within-run and total imprecision ranged from 3.1 to 4.7 %CV and 5.6 to 8.3 %CV, respectively, for levels ranging from 0.74 to 7.7 ng cTnI/mL.

CK-MB – Within-run and total imprecision ranged from 6.3 to 7.8 %CV and 7.7 to 8.9 %CV, respectively, for levels ranging from 3.63 to 109.9 ng CK-MB/mL.

Myoglobin – Within-run and total imprecision ranged from 6.1 to 7.5 %CV and 7.0 to 7.8 %CV, respectively, for levels ranging from 36 to 376.2 ng myoglobin/mL.

Analytical Sensitivity: The lowest detectable levels of cardiac troponin I, CK-MB, and myoglobin distinguishable from zero with 95% confidence are 0.04, 0.41, and 2.8 ng/mL, respectively.

Dilution Recovery (Linearity): Linearity studies performed by diluting sodium heparin plasma samples with plasma containing normal endogenous level of analyte provided average recoveries for cardiac troponin I, CK-MB, and myoglobin of 99.7 %, 99.2 %, and 100.9 %, respectively.

Method Comparison: Comparison of results obtained with 70 to 77 cardiac specimens to those obtained by the predicate methods yielded the following statistics:

> Cardiac troponin I – for concentrations ranging from 0 to 99 ng cTnI/mL in 101 specimens, good agreement was obtained with the $r = 0.9953$ and $y = 0.992x + 0.316$ ng/mL.
>
> CK-MB – for concentrations ranging from 2.35 to 341 ng CK-MB/mL in 73 specimens, good agreement was obtained with the $r = 0.995$ and $y = 0.995x + 0.313$ ng/mL.
>
> Myoglobin – for concentrations ranging from 12 to 710 ng myoglobin/mL in 70 specimens, good agreement was obtained with the $r = 0.985$ and $y = 0.965x + 6.5$ ng/mL.

Analytical Specificity: There was no significant interference from therapeutic drugs, biological substances, or heterophilic specimens. There was no significant cross-reactivity with other potential cardiac contractile proteins or CK isoenzymes.

Stability: Accelerated stability studies indicate that unopened Cardiac Panel reagent cartridges are stable for one year when stored at 2-8 °C. After opening, the reagent cartridges are stable for 24 hours at ambient temperature.

Reference Intervals: The 97.5th percentile upper range limit (URL) for troponin I is less than 0.15 ng/mL (functional sensitivity limit). Reference Intervals for CK-MB is 0.41 to 5.51 ng CK-MB/mL. For myoglobin, the Reference Interval for males is 8.2 to 101.5 ng myoglobin/mL and for females is 4.5 to 42.2 ng myoglobin/mL.

Cardiac Troponin I Functional Sensitivity: The functional sensitivity for cardiac troponin I at 20 % imprecision is 0.15 ng cTnI/mL.

Conclusion

The BioCentrex Cardiac Panel test system is substantially equivalent to the Access® AccuTnI™, Access® CK-MB, and Access® Myoglobin on the Access® Immunoassay Systems for the measurement of cardiac troponin I, CK-MB, and myoglobin in human blood, plasma, and serum.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 12 2004

Thomas H. Grove, Ph.D.
President
BioCentrex LLC
6100 Bristrol Parkway
Culver City, CA 90230

Re: k033155
Trade/Device Name: BioCentrex Cardiac Panel
Regulation Number: 21 CFR 862.1215
Regulation Name: Creatine Phosphokinase/Creatine Kinase or Isoenzymes Test System
Regulatory Class: Class II
Product Code: MYT, MMI, JHX, DDR
Dated: December 11, 2003
Received: December 12, 2003

Dear Dr. Grove:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

VI. INDICATIONS FOR USE

510(k) Number: K033155

Device Name: BioCentrex Cardiac Panel

Indications for use: For *in vitro* diagnostic use with the BioCentrex Analyzer to measure cardiac troponin I, creatine kinase-MB, and myoglobin from whole blood, serum or plasma specimens to aid in the diagnosis and treatment of patients with myocardial infarction.

Carol C Benson for Jean Cooper, DVM

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K033155

(PLEAST WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ___
(Per 21 CFR 801.109) (Optional Format 1-2-96)